PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 47956/301791	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/US2005/038519	International filing date *(day/month/year)* 25.10.2005	Priority date *(day/month/year)* 25.10.2004
International Patent Classification (IPC) or national classification and IPC INV. A61F2/06		
Applicant ALVEOLUS, INC. et al		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 8 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 4 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☒	Box No. VI	Certain documents cited
☒	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
03.10.2006	14.11.2006
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer PRECHTEL, A Telephone No. +49 89 2399-2332

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US2005/038519

Box No. I Basis of the report

1. With regard to the **language**, this report is based on

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3(a) and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4(a))
   - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1, 3-8	as originally filed
2, 2a	filed with the demand

Claims, Numbers

16-23	as originally filed
1-15	filed with the demand

Drawings, Sheets

1/2, 2/2	as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 11-23

because:

☒ the said international application, or the said claims Nos. 17-23 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*.

☒ no international search report has been established for the said claims Nos. 11-23

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b) and 13*ter*.2.

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☒ See separate sheet for further details

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US2005/038519

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	2-5,10
	No:	Claims	1,6-9
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-10
Industrial applicability (IA)	Yes:	Claims	1-10
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

   and / or

2. Non-written disclosures (Rule 70.9)

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item III.

- **Claims 17-23** deal with a method of removing or repositioning a stent within a lumen, which inevitably constitutes a surgical act. Therefore the subject-matter of these claims has not been searched (Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery) and no examination is carried out (Rule 67.1 (iv) PCT).

- **Claims 11-16** are not unitary with **claims 1-10** and have not been searched and no examination is carried out (Rule 66.1(e) PCT):

  Two separate groups of inventions are covered by the claims:

  1. **Claims 1-10**: a stent with an intertwined element comprising an engageable member in such a way that applying a force to the engageable member does not result in purse-stringing.

  2. **Claims 11-16**: a stent with engageable members arranged circumferentially about one of the stent's ends and one element disposed through the members in such a way that applying a force to the element results in purse-stringing.

  They are not linked to form a single general inventive concept (Rule 13.1 PCT) for the following reasons:

  Prior art document **D4= US5749921 A** discloses a stent comprising engageable members in such a way that applying a force to one engageable member does not result in purse-stringing.

  The common concept linking the two groups of inventions is a stent with engageable members. This concept is known from **D4**, therefore it is neither novel nor inventive. Since the claims are not linked by one single inventive concept, the requirement of unity is not met (Rule 13.1 PCT).

  For the first invention, the problem with respect to the prior art is to find an alternative to the way of fixing the engageable members to the stent. The solution is to provide engageable members that are fixed by intertwining around the stent struts, therefore the special technical feature is the intertwined

element.

Regarding the second invention, when a stent is to removed in the prior art, the diameter of the stent is reduced by pulling a plurality of threads (Fig. 7 of **D4**). Coordination of this plurality of threads is cumbersome and the problem is to find an easier way of reducing the diameter . The solution is to provide an element passing through the engageable members arranged circumferentially around the stent, thereby providing a loop that will reduce the diameter of the stent in a purse-string mechanism. The special technical feature is the element passing circumferentially through the engageable members.

These special technical features (intertwined element, element passing circumferentially through the engageable members) are not the "same or corresponding" within the meaning of Rule 13.2 PCT, so the requirement of unity (Rule 13.1 PCT) is not met.

Re Item V.

1. Reference is made to the following documents:

D1 : US 2003/149475 A1 (HYODOH HIDEKI ET AL) 7 August 2003
D2 : EP 0 701 800 A (C.R. BARD, INC) 20 March 1996
D3 : US 2002/040236 A1 (LAU LILIP ET AL) 4 April 2002
D4 : US 5 749 921 A (LENKER ET AL) 12 May 1998
D5: US-B1-6 241 757 (AN SUNG SOON ET AL) 5 June 2001

2. INDEPENDENT CLAIM 1

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of **claim 1** is not new in the sense of Article 33(2) PCT.
Document **D2** discloses:

"A removable stent for placement within a lumen (stent/anchor 14R in Figs. 35-38) comprising: a scaffolding of struts configured to define a substantially cylindrical member having a proximal end and a distal end (struts/wire segments 18 in Figs. 35-38), the stent further comprising:

and at least one flexible element spirally wound along at least a portion of a respective strut (element/hook 142 with torsion spring 144 is spirally wound around the struts/wire segments 18 in Figs. 35, 36; col. 19, line 27-col. 20, line 17.),
wherein the element comprises at least one engageable member (the engageable member/hook is engageable with the vessel wall)
such that a force applied to the engageable member does not result in purse-stringing (applying a force to engageable member/hook will not circumferentially constrict the stent and reduce its diameter, i.e. purse-stringing)."

It might be argued that **claim 1** is novel over **D2** since a torsion spring is not made of flexible material. However this is not convincing, since the expression "flexible" refers to a material that is "*able to revert to original size and shape after being stretched, squeezed, or twisted <used a flexible plastic for the toy>*" (Merriam Webster Online Thesaurus, http://m-w.com) and "*may or may not be resilient or elastic but which can be bent or folded without breaking <flexible plastic tubing>*" (Merriam Webster Online Dictionary, http://m-w.com). A torsion spring is therefore clearly made of a flexible material.

3. DEPENDENT CLAIMS 2-9

Dependent claims 2-8 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT) as all their features are disclosed in documents

D1 (pars. [0020], [0021]; Fig. 31),
D2 (column 19, line 27 - column 20, line 29; Figs. 1, 35-38),
D3 (pars. [0135]-[0137]; Figs. 17, 18),
D4 (column 5; Fig. 5) or
D5 (column 9, lines 53-61; Fig. 15).

Re Item VI.

Certain published documents

Application No Patent No	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date *(valid claim)* *(day/month/year)*
WO 05/79705	01-09-2005	09-02-2005	**11-02-2004**

Disclosed is a stent with an anchoring clip comprised of a wire intertwined with the struts of the stent.

Re Item VII.

- Independent **claim 1** is not in the two-part form ("characterised by") contrary to Rule 6.3(b) PCT.

Re Item VIII.

The requirements of Article 6 PCT are not met. In **claim 9** it is not clear what limitation the term "suture material" imparts upon the flexible element as surgical sutures may be made of a huge variety of materials, in particular steel or Nitinol wires. Since such a wire is also used as a hook with torsion spring in **D2**, this also leads to lack of novelty.

when the wire or thread is guided or braided in multiple windings around the support frame, a high degree of friction results between the two stent components, which has a disadvantageous effect on the explantation process. In addition, stents having eyelets for looping the thread therethrough may have sharp edges that cause the thread to tear or break during the removal process.

Alternatively, physicians have grasped the thread ends with forceps or a similar instrument to reposition or remove the stent from within the lumen. However, this can be complex at times when the tissue has grown over the suture thread. Also, the suture may not be strong enough to remove the stent. Grasping may lead to damage to the stent itself, as the forceps may have difficulty accessing or adequately gripping the thread to remove or reposition the stent. Physicians may also use grasping forceps to grab the struts of the stent at a proximal end and remove the stent from the deployment site, but this also risks damage to the lumen or the stent, as the proximal end of the stent may be difficult to access.

Various techniques have been developed for positioning or removing a stent within a lumen. For example, U.S. Patent Application Publication No. 20030149475 to Hyohoh et al. discloses a reinforcement wire (510) passing outside a biodegradable body, wherein the wire is threaded in and out of openings in the body 500 (see Figure 31). Hyohoh also discloses that the ends of the reinforcement wire may be secured to the body with loops (550) or other means, such as tying or twisting. Moreover, the reinforcement wire is described as being formed of a shape memory material, such as nitinol, that can be activated to pull the ends (560) and (570) of the body together, resulting in a tighter weave.

European Patent No. EP0701800 to C.R. Bard, Inc. discloses a synthetic vascular graft (12) and anchor assembly attached thereto. The anchor assembly is used to retain the graft in position within the lumen. More specifically, the anchor assembly may include a pair of anchors (14R, 14I) that consists of a wire configured in a zigzag pattern such that the anchors may resiliently expand into engagement with the lumen when deployed. In addition, the anchors may include hooks (24) that dig into the lumen wall to prevent migration. The anchors may

also be retracted such that the graft is insertable within a tubular delivery device for deployment and removal.

U.S. Patent Application Publication No. 20020040236 to Lau et al. discloses a procedure for folding and deploying an expandable stent. The stent (122) generally includes a plurality of torsion members (104) that are held in a phased relationship using a flexible linkage (124). Lau also discloses that the stent may be folded for deployment. In particular, Lau discloses that the stent may be folded longitudinally and positioned within a lumen of a catheter for deployment. Moreover, tether lines (306) may be employed to maintain the stent in the folded configuration. Removing the tether lines from the loops (308) unfolds the stent so that the stent may be expanded to a cylindrical shape within the lumen.

In addition, U.S. Patent No. 5,749,921 to Lenker et al. discloses an apparatus and method for compressing an endoluminal prosthesis. In particular, Lenker discloses a plurality of filament loops (58) that extend through a shaft (34) and loop around a frame (74) of a prosthesis (72). Tensioning the filament loops causes the prosthesis to compress inwardly such that moving the shaft 34 distally compresses the remainder of the prosthesis. To deploy the prosthesis, the filament loops are typically cut and removed from the prosthesis.

Moreover, U.S. Patent No. 6,241,757 to An et al. discloses a stent that is formed by winding a single filament wire in a zigzag and/or spiral pattern. FIG. 15 of An discloses a retrieving member that facilitates retrieval of the stent. The retrieving member includes fixed nylon wires (52) connected to the filament and retrieving wires (54) supported by the fixed wires.

Thus, there is a need in the industry for a stent that reduces the risk of damage to the stent, thread or suture, and/or the surrounding tissue during removal or repositioning of the stent. In addition, there is a need for a stent that provides for greater accessibility, as well as promotes effective repositioning and/or removal of the stent from a lumen.

THAT WHICH IS CLAIMED:

1. A removable stent (10) for placement within a lumen comprising a scaffolding of struts (12, 14) configured to define a substantially cylindrical member having a proximal end and a distal end, the stent further comprising:

at least one flexible element (16) spirally wound along at least a portion of a respective strut, wherein the element comprises at least one engageable member such that a force applied to the engageable member does not result in purse-stringing.

2. The stent according to Claim 1, wherein the struts comprise a plurality of interconnected legs arranged circumferentially about the stent and a plurality of connectors interconnecting the legs and extending along a longitudinal axis of the stent.

3. The stent according to Claim 2, wherein at least a portion of each element is wound longitudinally along a plurality of connectors in a spiral-like configuration.

4. The stent according to Claim 2, wherein at least a portion of the element is wound circumferentially along a plurality of legs in a spiral-like configuration.

5. The stent according to Claim 2, wherein each element is spirally wound about a plurality of legs and connectors, and wherein free ends of each element are joined together to define an engageable member.

6. The stent according to Claim 1, wherein at least a portion of each element is wound proximate to the proximal or distal ends of the scaffolding.

7. The stent according to Claim 6, wherein a free end of each element proximate to the proximal or distal ends is configured as an engageable member.

8. The stent according to Claim 1, wherein at least a portion of the engageable member extends proximally from the proximal end or distally from the distal end.

9. The stent according to Claim 1, wherein the at least one element comprises a flexible suture material.

10. The stent according to Claim 1, wherein the at least one engageable member comprises a loop.

11. A removable stent for placement within a lumen comprising:

a scaffolding of struts configured to define a substantially cylindrical member having a proximal end and a distal end; and

a plurality of engageable members arranged circumferentially about at least one of the proximal and distal ends; and

at least one element disposed within each of the engageable members and about the circumference of the proximal or distal end, wherein a force applied to the element at the proximal or distal end causes the proximal or distal end to reduce in diameter.

12. The stent according to Claim 11, wherein at least a portion of each of the engageable members is intertwined about at least a portion of the struts.

13. The stent according to Claim 11, wherein each of the engageable members is attached to an outer periphery of the proximal or distal end.

14. The stent according to Claim 11, wherein each of the engageable members extends proximally from the proximal end or distally from the distal end.

15. The stent according to Claim 11, wherein the plurality of engageable members and at least one element comprise a suture material.

PATENT COOPERATION TREATY

PCT

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43*bis*.1)

Applicant's or agent's file reference see form PCT/ISA/220	Date of mailing *(day/month/year)* see form PCT/ISA/210 (second sheet) **FOR FURTHER ACTION** See paragraph 2 below

International application No. PCT/US2005/038519	International filing date *(day/month/year)* 25.10.2005	Priority date *(day/month/year)* 25.10.2004

International Patent Classification (IPC) or both national classification and IPC
INV. A61F2/06

Applicant
ALVEOLUS, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Prechtel, A-K Telephone No. +49 89 2399-2332

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2005/038519

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ in written format

   ☐ in computer readable form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2005/038519

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 17-23, 11-16

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the whole application or for said claims Nos. 17-23, 11-16

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	☐	has not been furnished
	☐	does not comply with the standard
the computer readable form	☐	has not been furnished
	☐	does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2005/038519

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☒ not paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

   see separate sheet

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-10

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1-10
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-10
Industrial applicability (IA)	Yes:	Claims	1-10
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43*bis*.1 and 70.10)

   and / or

2. Non-written disclosures (Rules 43*bis*.1 and 70.9)

   see form 210

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item III.

Claims 17-23 deal with a method of removing or repositioning a stent within a lumen, which inevitably constitutes a surgical act. Therefore the subject-matter of these claims has not been searched (Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery).

Re Item IV.

Two separate groups of inventions are covered by the claims:

1. **Claims 1-10**: a stent with an intertwined element comprising an engageable member in such a way that applying a force to the engageable member does not result in purse-stringing.

2. **Claims 11-16**: a stent with engageable members arranged circumferentially about one of the stent's ends and one element disposed through the members in such a way that applying a force to the element results in purse-stringing.

They are not linked to form a single general inventive concept (Rule 13.1 PCT) for the following reasons:

Prior art document **D4= US5749921 A** discloses a stent comprising engageable members in such a way that applying a force to one engageable member does not result in purse-stringing.

The common concept linking the two groups of inventions is a stent with engageable members. This concept is known from **D4**, therefore it is neither novel nor inventive. Since the claims are not linked by one single inventive concept, the requirement of unity is not met (Rule 13.1 PCT).

For the first invention, the problem with respect to the prior art is to find an alternative to the way of fixing the engageable members to the stent. The solution is to provide engageable members that are fixed by intertwining around the stent struts, therefore the special technical feature is the intertwined element.

Regarding the second invention, when a stent is to removed in the prior art, the diameter of the stent is reduced by pulling a plurality of threads (Fig. 7 of **D4**). Coordination of this plurality of threads is cumbersome and the problem is to find an easier way of reducing the diameter . The solution is to provide an element passing through the engageable members arranged circumferentially around the stent, thereby providing a loop that will reduce the diameter of the stent in a purse-string mechanism. The special technical feature is the element passing circumferentially through the engageable members.

These special technical features (intertwined element, element passing circumferentially through the engageable members) are not the "same or corresponding" within the meaning of Rule 13.2 PCT, so the requirement of unity (Rule 13.1 PCT) is not met.

Re Item V.

1. Reference is made to the following documents:
   D1 : **US 2003/149475 A1** (HYODOH HIDEKI ET AL) 7 August 2003
   D2 : **EP 0 701 800 A** (C.R. BARD, INC) 20 March 1996
   D3 : **US 2002/040236 A1** (LAU LILIP ET AL) 4 April 2002
   D4 : **US 5 749 921 A** (LENKER ET AL) 12 May 1998
   D5: **US-B1-6 241 757** (AN SUNG SOON ET AL) 5 June 2001

2. INDEPENDENT CLAIM 1

2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of **claim 1** is not new in the sense of Article 33(2) PCT.
Document **D1** discloses:

"A removable stent for placement within a lumen (stent 500 in Fig. 31, par. [0021]) comprising:
a scaffolding of struts configured to define a substantially cylindrical member having a proximal end and a distal end (struts/filaments 540 in Fig. 31, pars. [0239], [0319]) ;
and at least one element intertwined about at least a portion of the struts (element/reinforcement wire 510 in Fig. 31, par. [0220]) ,
wherein the element comprises at least one engageable member (engageable member/loop 550

in Fig. 31, par. [0220]: "*loops 550 may also be used in securing body 500 to a delivery system*")
such that a force applied to the engageable member does not result in purse-stringing (Applying a force to member/loop 550 will warp the stent but will not circumferentially constrict the stent and reduce its diameter, i.e. purse-stringing)."

It should be noted that the subject-matter of **claim 1** is also disclosed in prior art documents **D2, D3, D4** or **D5**.

3. DEPENDENT CLAIMS 2-9
Dependent claims 2-8 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT) as all their features are disclosed in documents **D2, D3, D4** or **D5** (see search report).

Re Item VI.

Certain published documents

Application No Patent No	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date *(valid claim)* *(day/month/year)*
WO 05/79705	01-09-2005	09-02-2005	**11-02-2004**

Disclosed is a stent with an anchoring clip comprised of a wire intertwined with the struts of the stent.

Re Item VII.

- Independent **claim 1** is not in the two-part form contrary to Rule 6.3(b) PCT.
- The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

- The relevant background art **D1-D4** is not disclosed (Rule 5.1(a)(ii) PCT).

Re Item VIII.

In **claim 9** it is not clear what limitation the term "suture material" imparts upon the element as the range of material that can be used as suture material ranges from flexible and pliable threads to inflexible wires like those used in **D1.** Therefore the requirement of Article 6 PCT is not met.